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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,124	07/07/2004	Hirota Uzawa	TIP 026	6055

7590 06/01/2005

Gary C Cohn PLLC
1147 NORTH FOURTH STREET
UNIT 6E
PHILADELPHIA, PA 19123

EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,124

Applicant(s)

UZAWA ET AL.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/2004</u> : | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-4 are pending in this action.

Claim Objections

Claim 1 is objected to. The claim language in parentheses should be rewritten as “wherein G represents an oligosaccharide radical composed of two to thirty monosaccharides, and wherein R represents a hydrocarbon group containing six to thirty-five carbons.” The parentheses should be omitted from the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

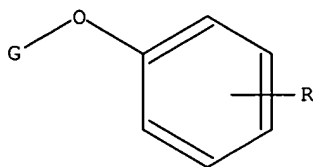
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al., Shimizu et al., Hinz et al. and Mathew et al.

Claims 1-4 are directed to a nano-scale self-aggregate comprising O-glycoside type oligolipid having a structure represented by the general formula 1:



Wherein G represents an oligosaccharide radical composed of two to thirty monosaccharides, and R represents a hydrocarbon group containing six to twenty-five carbon atoms; wherein the hydrocarbon group R is located in a meta position relative to the -O-G group; wherein the oligosaccharide is a disaccharide; wherein the oligosaccharide is lactose.

John et al. teach monosaccharide compounds of the variety that are claimed by the applicant with all the limitations pertaining thereto in regard to the variable R, its position, and the phenol group to which it is attached as well as a monosaccharide in the G position (see p. 715 first column figure 1). John et al. does not teach oligosaccharides, disaccharides or lactose in the G position.

However, John et al. does teach that “[t]he interdigitated glycolipids are very similar in structure to a conventional bola-amphiphile, with an oligomethylene spacer and two amide linkages at either end and sugar moieties as head groups” thereby suggesting that plural sugars can be used as head groups. John et al. further states that the head group conformation has a remarkable effect on the helical morphologies of nano fibers formed with peptide lipids (see p. 716 first full paragraph) and refers to Shimizu et al. in the endnotes. These statements would motivate one skilled in the art to consult Shimizu et al. in attempting to modify the head group.

Shimizu et al. teaches that oligosaccharides can be used as head groups (see p. 50 column 2 first full paragraph) and then refers to Hinz et al. for the specific teaching of which oligosaccharides and disaccharides can be substituted as head groups. Hinz et al. teach “single

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sugar moieties and more so oligosaccharides can present a remarkable variety of configurations and structures in relatively short chains by the multiple choices of isomer linkages and branching patterns” (see p. 5125 second column). Hinz et al. also teach oligosaccharide and disaccharide head groups (see p. 5126 figure 1). The Hinz et al. reference would motivate one skilled in the art to attempt to utilize oligosaccharide and disaccharide compounds to substitute in the G position. Hinz et al. though does not teach lactose in the G position; however, one skilled in the art would consult Mathews et al. for suitable disaccharides such as lactose to substitute in the G position (see pp. 299-306).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings above to obtain the compound as claimed in the instant application. All of the moieties, which are substituted in the instant application, are taught in the art, and the locations of substitution are correlative with the locations of substitution in the art. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new nano-scale self aggregates. See *In re Payne*, 203 USPQ 245 (CCPA 1979).

Conclusion

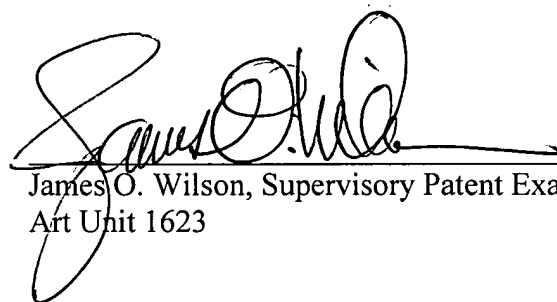
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O.

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Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., Esq.



James O. Wilson, Supervisory Patent Examiner
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